

### **REMARKS**

This is in response to the official action dated January 31, 2012. Reconsideration in view of the following is respectfully requested.

### **Claim Status**

Claims 12-15 and 25-35 are pending in the application and stand rejected. Claims 1-11, and 16-24 were cancelled. Claims 25-38 have been newly added.

### **Sequence Compliance/CRF Sequence Listing**

A Substitute Copy of the Sequence Listing in Computer readable form/TXT format is enclosed.

Applicants hereby state that the information recorded in computer readable form/ TXT format is identical to the paper/PDF version of the Sequence Listing filed 27 May 2008.

No new matter has been added.

### **Specification Amendments**

In order to provide *ipsis verbis* antecedent basis for the original claims in the specification, the substance thereof has been incorporated into the specification. The term “claim” has been changed to “item” for reasons of clarity.

The amendment to the specification to incorporate the substance of the original claims does not introduce new matter. See MPEP § 608.01(l).

### **Claims Amendments**

The amendments find support in the specification as follows:

- Claim 25      Page 5, 4<sup>th</sup> paragraph through page 6, 1<sup>st</sup> paragraph (production of specific anti-elastase antibodies, carrier connected to peptide, polyclonal antibodies by immunization of animals, monoclonal antibodies by inducing specific B-cell, fusion of myeloma cells, and generation of hybridoma cells, cloning and cultivating);
- Sequence listing,
- Items 1, 2, 4, 7, 8, 10/11, and 16 of the amended specification.
- Claim 26-27      Page 4, 1<sup>st</sup> paragraph, lines 2-3;
- Items 8 and 9 of the amended specification (various animals for immunization).
- Claim 28      Page 3, 3<sup>rd</sup> paragraph, line 7 (carrier proteins such as haemocyanine);
- Item 8 of the amended specification (haemocyanine and albumin carriers).
- Claim 29      See claim 25
- Claim 30      Page 4, bottom third of the page/sentences following the ones with the peptide sequences (identification of functional disorders of the pancreas);
- Page 5, 1-5<sup>th</sup> paragraph (diagnosis of pancreas disorders);
- Page 6, 1<sup>st</sup> -2<sup>nd</sup> paragraphs (antibodies, identification and quantification of elastase in body fluids);
- Examples 3 and 6 (binding of antibodies, detection);
- Sequence listing (peptides);
- Items 1 (diagnostic procedure), 5 (antibodies used singly or in combination), 6 (diagnosis or progress check using one or more antibody) and 16 (purification and detection with at least one antibody) of the amended specification (diagnostic procedures to identify pancreas disorder).
- Claim 31&32      Page 4, bottom third of the page (bodily fluids, stool);

Page 5, line 1 (stool, serum, plasma);

Examples 3 and 6 (stool) and example 5 at page 6 line 6 (pancreatic juice),

Items 1, 6, 7, and 17 of the amended specification (serum, secretions, excretion; stool or body fluids).

Claim 33, 36-38 Page 4, last three sentences & Page 6, 2<sup>nd</sup> paragraph (Sandwich-ELISA, immune-chemical identification system, antibody connected to carrier, coupling procedure, suitable carriers/membranes for adsorptively or chemically coupled antibodies include membranes or particles);

Examples 3 (fixed phase sandwich ELISA with antibodies adsorbed on microtiter plate, conjugation of 2<sup>nd</sup> antibody to biotin for detection), 4 (ELISA on free [of antibody], fixed-phase peptides directly adsorbed to microtiter plate), 5 (ELISA on membrane-bound elastase) and 6 (fixed-phase sandwich ELISA using individual or mixture of anti-elastase antibodies adsorbed onto a microtiter plate, detection with biotin-conjugated anti-elastase antibodies);

Items 1, 5, 16 and 18 of the amended specification.

Items 1 (diagnostic procedure), 5 (antibodies used singly or in combination in immunochemical identification system), 6 (detection system), 16 (containing at least one of the antibodies) of the amended specification and 18 (test kits with two different antibodies/Sandwich ELISA).

Claim 34 Page 5, 4<sup>th</sup> paragraph (peptide sequences binding specifically),

Example 1 at page 7 (ELISA using antibodies from animals immunized with carrier (haemocyanine)-coupled peptides),

Items 5 (antibodies used singly or in combination), 6 (immunological test kit), 7 (antibodies by immunization of animals), 8 (carrier-coupled peptides including haemocyanine and albumin), 10 (polyclonal antibodies), 16 (detection system) and 17 (immunological test kit for diseases of the pancreas or mucoviscidosis) of the amended specification.

Claim 35           Page 4, bottom third of the page; Page 6, 2<sup>nd</sup> paragraph; Examples 3, 4 and 6; Items 6 (immunological test kit), 17 (immunological test kit for diseases of the pancreas or mucoviscidosis), and 18 (Sandwich ELISA with two different antibodies) of the amended specification.

The claim amendments do not introduce new matter.

### **Deviations from Examiner's suggested claims**

The following claims have been adjusted for reasons of preference:

Claim 25: “(comprising) the steps of”, “wherein the peptide is (selected from)”, “thereby inducing”, “the (antibodies)”.

Claim 26: “(selected from) the group consisting of”

Claim 29: “(comprising) the steps of”, “wherein the peptide is (selected from)”, “thereby inducing”, “(obtaining) isolated polyclonal antibodies [by separating and purifying]”.

Claim 30: Deleted “disorder (of pancreatic function)” and “(patient) at risk for or suspected of having a disorder of pancreatic function”. Compare the specification at page 5, 2<sup>nd</sup> paragraph: “It [the invention] can also be used for the diagnosis or to establish **the absence** of pancreas involvement in abdominal complaints and exocrine pancreas sufficiency.”

Added “the identification or the (amount of a human pancreatic elastase iso-enzyme)”. Compare the specification at page 5, 3rd paragraph: “ There are also cases in which the **detection of elastase 1 is in itself sufficient** to permit a certain diagnosis of pancreas disorders.”

Added ““the method (comprising) the steps of”, “(elastase) isoenzymes”.

Claim 33: Added “(two different) anti-elastase iso-enzyme (antibodies)”; replaced “reacted” with “brought into contact”. Replaced “a solid phase carrier immobilized at least one of the antibodies and a detectably labeled at least different one of the antibodies” with “a specific anti-elastase

isoenzyme antibody immobilized onto a fixed phase and detected with a suitable detection system”.

Claim 35: Replaced “for performing” with “adapted to perform”.

Added Claim 36: ELISAs including but not limited to the “Sandwich ELISA” format.

Added Claim 37: Sandwich ELISA with antibodies recognizing more than one elastase epitope, for example a mix of different specific antibodies, or specific “cross-reactive” antibodies that recognizes more than one elastase epitope.

Added Claim 38: Sandwich ELISA with specific “cross-reactive” antibodies, which recognize more than one elastase epitope.

#### **Claim Rejections - 35 USC § 112 2nd paragraph/Indefiniteness**

##### **Claims 1, 3, 6, 8, 9, 17-19 and 24**

The claims have been cancelled. Newly added claims 25-38 essentially follow the Examiner’s suggestions.

#### **Claim Objections - 35 U.S.C. § 112, 2nd paragraph/Indefiniteness**

The claims have been cancelled. Newly added claims 25-38 essentially follow the Examiner’s suggestions.

#### **Claim Objections - Informalities**

The objected-to claims 1, 3, 6, 8, 9, 17-19 and 24 have been cancelled. Newly added claims 25-38 essentially follow the Examiner’s suggestions. In particular, the sequence SEQ ID NO:4 is listed in the computer readable form of the Sequence Listing, which is filed herewith.

Objected-to claims 12-15 have been amended adding the missing “-“ for consistency.

### **Prior Art**

In response to Examiner's assertions with regard to the prior art on page 10-12 of the Office Action, the Applicants make reference to the earlier remarks in the Applicants' previous response. Prior claims are cancelled without prejudice. Applicants reserve the right to file a divisional application for subject matter not covered by present claims.

Notably, present claims are directed to novel synthetic peptides and antibodies raised against conjugates of certain peptides with a non-elastase carrier protein, and methods employing such synthetic peptides or conjugates, none of which could have been inherently present in a random preparation of purified or fragmented elastase enzyme.

None of the prior art documents alone or in combination discloses or suggests the claimed peptides of the present invention or the claimed methods employing them, nor achieves the specificity in detecting elastase isoenzymes.

### **CONCLUSION**

The instant application is believed to be in condition for allowance. A Notice of Allowance for the claims is respectfully requested. The Examiner is invited to telephone the undersigned at (212) 808-0700 if it is believed that further discussions, and/or additional amendment would help advance the prosecution of the instant application.

### **CONDITIONAL PETITION FOR EXTENSION OF TIME**

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

**ADDITIONAL FEE**

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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